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मानक

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“Step Out From the Old to the New”

IS 4085 (1967): Knives, Amputating [MHD 1: Surgical Instruments]



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Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

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IS : 4085 - 1967
(Reaffirmed 1996)

REAFFIRMED

2006

Indian Standard
**SPECIFICATION FOR
KNIVES, AMPUTATING**

(Second Reprint JUNE 1999)

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

AMENDMENT NO. 1 JULY 1975
TO
IS:4085-1967 SPECIFICATION FOR
KNIVES, AMPUTATING

Alterations

(Page 5, clauses 8.3 and 8.3.1) - Substitute the following for the existing clauses:

'8.3 Corrosion Resistance - The instrument shall satisfy the boiling and autoclaving test as mentioned in IS:7531-1975*

(Page 5, foot-note) - Insert the following foot-note at the bottom of the page:

*Method for boiling and autoclaving test for corrosion resistance of stainless steel surgical instruments

(CPDC 11)

Indian Standard

SPECIFICATION FOR KNIVES, AMPUTATING

Surgical Instruments Sectional Committee, CPDC 11

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

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Indian Standard

SPECIFICATION FOR KNIVES, AMPUTATING

0. FOREWORD

0.1 This Indian Standard was adopted by the Indian Standards Institution on 20 April 1967, after the draft finalized by the Surgical Instruments Sectional Committee had been approved by the Consumer Products Division Council.

0.2 The formulation of Indian Standards on surgical instruments has been taken up on the recommendations of the Advisory Committee for Development of Medical Instruments, Equipment and Appliances of the Government of India.

0.3 This Indian Standard is one of a series on surgical instruments.

0.4 In preparing this standard, assistance has been derived from IND/GS/MED 98(b) 'Knives, amputating — 6 in blade' published by the Chief Inspectorate of General Stores, Ministry of Defence, Government of India.

0.5 Indian Standard general requirements for surgical scalpels and knives (IS : 3318-1965†) forms an adjunct to this standard generally, but the provisions laid down herein shall prevail.

0.6 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This Indian Standard specifies the requirements for knives used in amputation.

2. MATERIALS

2.1 High carbon steel used for the manufacture of knives shall have the composition as specified in 2.2 of IS : 3318-1965†.

*Rules for rounding off numerical values (*revised*).

†General requirements for surgical scalpels and knives.

IS : 4083 - 1967

2.2 Stainless steel used shall have the composition as given in 2.4 of IS : 3318-1965*.

3. SHAPE AND DIMENSIONS

3.1 The shape and dimensions of the different sizes of amputating knives shall be as shown in Fig. 1.

4. WORKMANSHIP AND FINISH

4.1 The knives shall be so forged as to be uniform on their central planes with the cutting edge on the central plane. The blade shall be hollow ground having a cutting edge with a cutting angle as shown in Fig. 1. The cutting edge shall be free from feathers, nicks, high spots, waviness and undulation. The blade shall be passivated and highly polished. The end of the blade shall be pointed and sharp. All edges except the cutting edge shall be rounded (*see also* IS : 3318-1965*)

4.2 The handles shall be either recessed or solid and without any bolster.

4.2.1 In the case of stainless steel knives, the handle shall be finished smooth with a matt finish.

4.2.2 In the case of high carbon steel knives, the handle shall be plated chromium over nickel. The thickness of the coating shall be as follows:

Nickel, <i>Min</i>	15 micron
Chromium, <i>Min</i>	0.25 micron

In all other respects, the plating shall conform to IS : 1068-1958†.

5. HEAT TREATMENT

5.1 The blades of the knives shall be uniformly hardened and tempered to 650 to 750 HV.

6. MARKING

6.1 The knives shall be clearly and indelibly marked with the manufacturer's name, trade-mark or identification mark. The marking shall be done on the handle and not on the blade.

6.1.1 The product may also be marked with Standard mark.

*General requirements for surgical scalpels and knives.

†Specification for copper, nickel and chromium electroplated coatings.

6.1.2 The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act, 1986* and the Rules and Regulations made thereunder. The details of conditions under which the licence for the use of Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

7. PACKING

7.1 The cutting edge and blade shall be clean and shall be given a suitable protective coating. Knives shall be wrapped individually in wax paper or polyethylene bags and packed in boxes in such a manner that they do not come in contact with each other.

8. TESTS

8.1 Uniformity of Cutting Edge — The cutting edge shall be examined under a magnification of at least **60 X** in two directions, along and perpendicular to the plane of the cutting edge, for feathers, nicks, waviness, etc.

8.2 Rigidity of the Blade — The handle of the knife shall be fixed in a vice so that the whole length of the blade protrudes from the vice in the horizontal plane. A load of 5 kg shall be applied to the blade at a distance of 30 mm from the tip of the blade. The load shall be applied gradually and allowed to act for two minutes. On completion of the test, the knife shall show no permanent set.

8.3 Corrosion Resistance Test — The amputation knife made of stainless steel shall be tested for corrosion resistance as prescribed in **8.3.1**.

8.3.1 Copper Sulphate Test — The sample shall be scrubbed with soap and warm water, rinsed in hot water, followed by a dip in ethyl alcohol (95 percent), and dried. The sample shall be completely immersed in copper sulphate solution at room temperature for 6 minutes and shall then be washed off with fresh water or wet cotton wool. The copper sulphate solution shall be made up as follows:

Copper sulphate	($\text{Cu SO}_4 \cdot 5\text{H}_2\text{O}$)	4.0 g
Sulphuric acid	(H_2SO_4) (Sp-gr 1.84)	10.0 g
Water	(H_2O)	90.0 ml

There shall be no red stains or spots on the sample after the test, but the polished surface getting dull may be permitted.

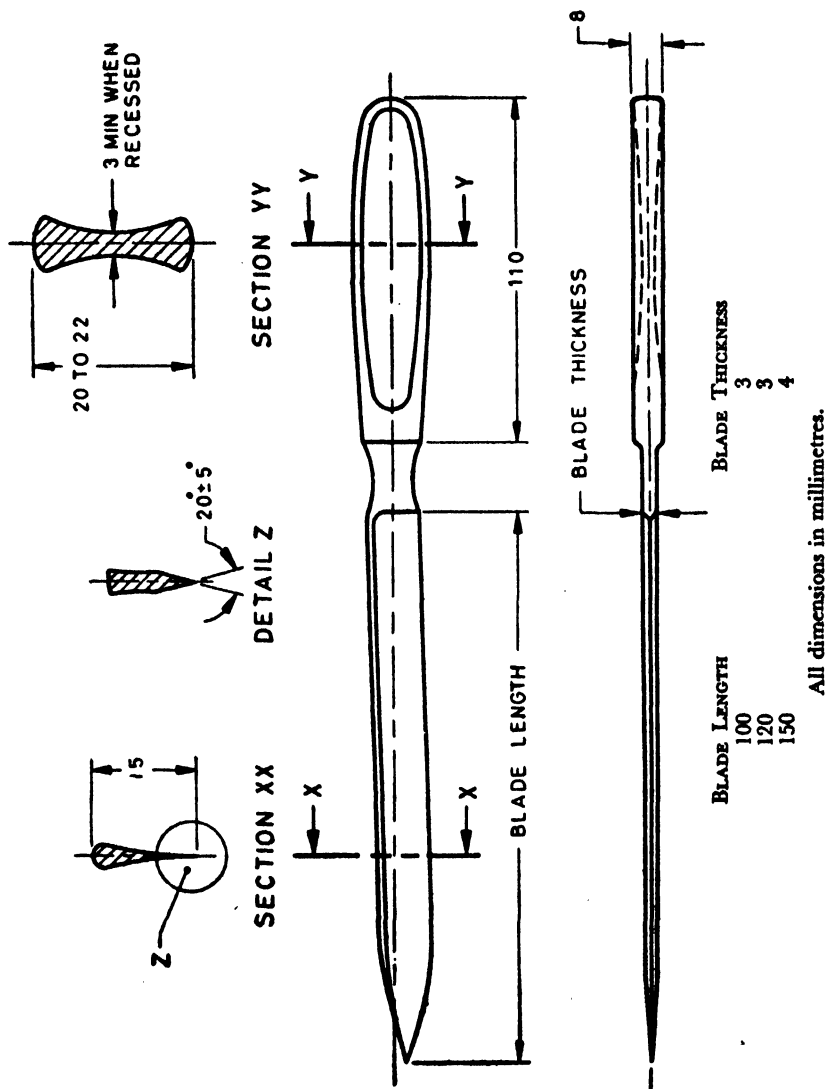


FIG. 1 AMPUTATING KNIFE, SINGLE EDGE

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